

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
31 March 2005 (31.03.2005)

PCT

(10) International Publication Number  
**WO 2005/027821 A3**

(51) International Patent Classification<sup>7</sup>: **C07K 17/00**,  
14/00, 1/00, A61K 35/14, 38/04, A23J 1/00

(21) International Application Number:  
PCT/IL2004/000881

(22) International Filing Date:  
22 September 2004 (22.09.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
158053 22 September 2003 (22.09.2003) IL  
60/503,902 22 September 2003 (22.09.2003) US

(71) Applicants (for all designated States except US): **KA-MADA LTD.** [IL/IL]; Science Park, Kiryat Weizmann, 76327 Rehovot (IL). **AMERICAN RED CROSS, PLASMA SERVICES** [US/US]; 2025 E. Street N.W., Washington, DC 20006 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **BAUER, Shabtai** [IL/IL]; 35 Shahal Street, 93702 Jerusalem (IL).

(74) Agent: **WEBB, Cynthia**; Webb & Associates, P.O. Box 2189, IL-Rehovot 76121 (IL).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:  
4 August 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: LARGE SCALE PREPARATION OF ALPHA-1 PROTEINASE INHIBITOR AND USE THEREOF

(57) Abstract: The present invention provides a process suitable for processing scaled-up amounts of source material in the range of tens of kilograms for the purification of alpha-1 proteinase inhibitor (API) from a mixture of unpurified proteins. More particularly, the present invention relates to a process for the purification of API from blood plasma or from plasma fractions to obtain pharmaceutical grade API on a commercial scale. The API produced by the process of the present invention is highly pure (at least 90% API out of the total protein) and highly active (at least 90% active API). The present invention also relates to pharmaceutical compositions comprising the purified API and methods of using same.

WO 2005/027821 A3